体外透皮实验指导意见

详细介绍 ：

本公司提供多种巴马猪皮，小乳猪皮等猪皮产品，符合CDE皮肤外用化学仿制药研究技术指导原则的要求 ，

联系人陈经理 15688483044

GB/T 27818—2011

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?????????????(OECD) ??????? No.428(2004)???????????(? ??)????????

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---?OECD428????“????”?“??”???????????

---?OECD428????“????”?“??”???????“4.10 ???????”;

---?OECD428????“?????”?“??”???????“5 ???????”;

---?OECD428??????“??”?????“2 ?????”;

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?????????????????????(SAC/TC 251)??????

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OECD ??????? No.428???????????(2004)(???)
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??????? ?????????????????????????????????

??? ???? ??????

1 ??

???

?? ?????????????????????????

2 ?????

???????????????

2.1

????? unabsorbed dose

???

???

2.2

????(????) absorbed dose;in vitro

?????????????????????????

2.3

?????(????) the absorbable dose;in vitro

????????????????????????

3 ????

???(????????)???????????????????? ????????????? ?? ??????????????????????

??? ???????????????????

??????????(2)?????????????????????????????????? ?? ????????????????????(???????????

???????? ???????????????

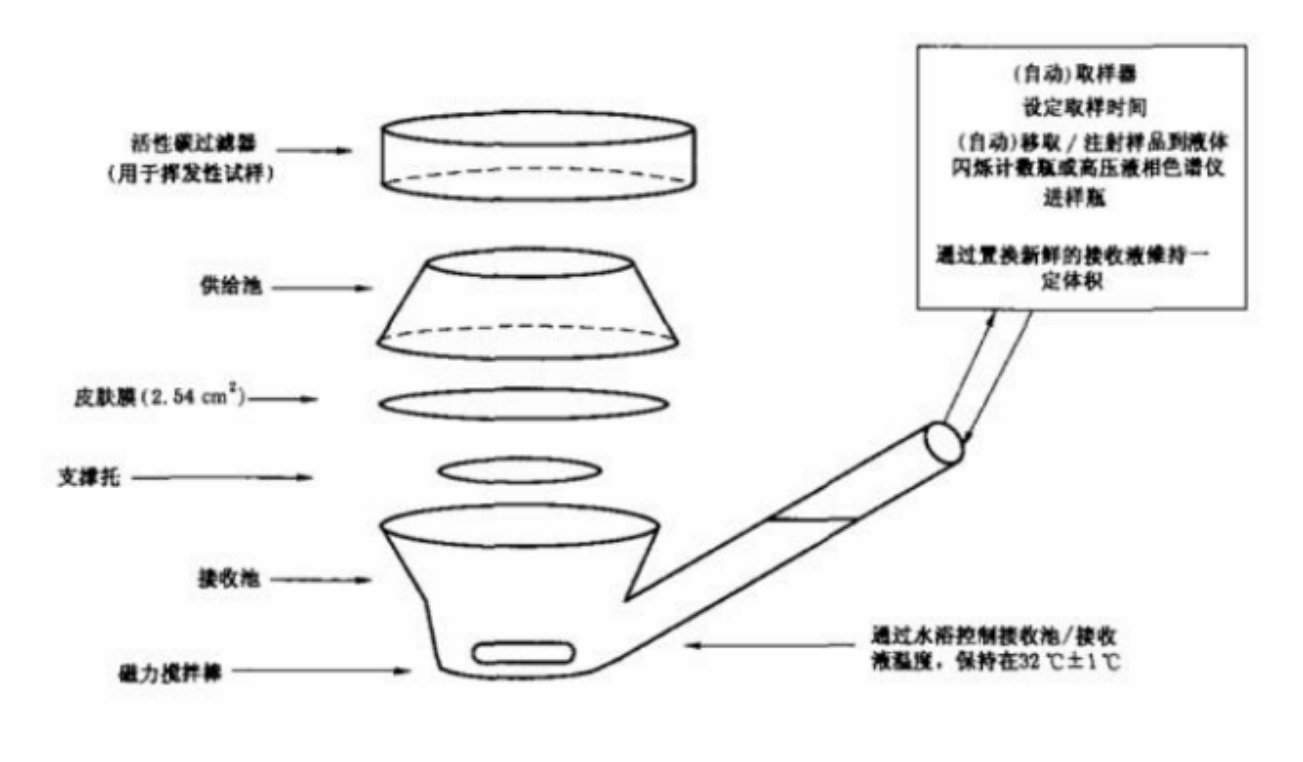
?? ?????????????????(???????????)????????????????? ????????(????????????)???????????

4 ????

4.1 ???

????????????????????(?1????????)???

????????????????????????????????????



? 1 ????????????????????????

4.2 ???
?? ???
?? ???

4.3 ????
??13???.????????????????????????????(?????????)??? ????????(????200 ?m?400?m ?)
??????????????(???1mm) ???

4.4 ?????
?? ???????????????24 h
????????????????????????????????????14?,????????????????????????????

4.5 ???
????????????????????????????????

4.6 ?????
?????(????????????????????????????)???????? ????????????(?????????)???????????????????

4.7 ????????
?? ????

4.8 ????
?? ??????1mg?5 mg??????10 ?L ?????????????????????????
?? ?????

4.9 ??
????????????????????????????????????(32?±1?)? ?????????????????????????????/????????????????? ???30%?70%???

4.10 ???????
????????????????????????????????(????????????)? ?? ???????????????????????????????????
h ??? ?????????24h ?????????????????24h? ????????????? ???????24 h,????????????????????????????????????? ?????????????????

4.11 ?????

?? ??/?? ???????????????????????????????
100± 10%,??????????),???????????????????????????????? ?????????

5 ???????

5.1 ??
?? ?????????????????????????(???????)????????????(??????????????)
???????????????????????????? ?? ??????(K,),?????????????

5.2 ????

??

5.2.1 ????

a) ?????????(???????????1gP ????)???(???????);

b) ????(???);

c) ??????????

5.2.2 ??????

a) ???????????

b) ????

5.2.3 ?????

a) ?????????????????????????????(?????????)????? ???????????????

b) ?????????????????????????????

c) ?????????????????????

d) ???????

e) ?????????????????????

f) ?????????????????????????

g) ????????????

h) ?????????????????????????

5.2.4 ???

a) ????????(????=?????+?????+??????????);

b) ???????????

c) ?????????

d) ??????(????????????????)?

5.2.5 ?????

5.2.6??

? ? ? ?

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